



Paige C. Magness
Senior Vice President
Regulatory Affairs

July 30, 2021

Via Electronic Submission
<https://www.reginfo.gov/public/do/PRAMain>

Re: Substance Abuse and Mental Health Services Administration Agency Information Collection Activities: Submission for OMB Review; Comment Request (86 Fed. Reg. 34,773, June 30, 2021).

Altria Client Services Inc. ("ALCS"), on behalf of Philip Morris USA Inc. ("PM USA), John Middleton Co. ("JMC"), U.S. Smokeless Tobacco Company LLC ("USSTC"), and Helix Innovations LLC ("Helix"),¹ submits these comments in response to the above-referenced request for information ("Request").

The tobacco product category continues to evolve rapidly, driven by adult consumer demand, regulatory pathway development, and manufacturer investments in products with the potential to reduce the harm associated with smoking. National surveys should be increasingly inclusive of emerging product categories and provide timely data publication to best inform policymaking and responsible product marketing.

The Substance Abuse and Mental Health Services Administration ("SAMHSA") administers the National Survey on Drug Use and Health ("NSDUH") survey. "NSDUH data are used to determine the prevalence of use of tobacco products...[t]he results are used by SAMHSA, the Office of National Drug Control Policy...federal government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources."²

¹ PM USA, JMC, and USSTC are wholly-owned subsidiaries of Altria Group, Inc. ("Altria"). Helix is a wholly-owned subsidiary of Altria Enterprises II LLC, which is a wholly-owned subsidiary of Altria. PM USA manufactures cigarettes and is licensed to sell and distribute IQOS® and HeatSticks® in the United States and JMC manufactures cigars and pipe tobacco. USSTC manufactures smokeless tobacco products and oral tobacco-derived nicotine products. Helix manufactures oral tobacco-derived nicotine products. ALCS provides certain services, including regulatory affairs, to the Altria family of companies. "We" and "our" are used throughout to refer to PM USA, JMC, USSTC, and Helix.

² Request at 34,773.

Periodically, SAMHSA updates NSDUH “to reflect changing substance use...and to continue producing current data.” For the 2022 NSDUH, SAMHSA proposes to “replac[e] the tobacco module with a redesigned nicotine module that includes questions about vaping...”³

We have frequently advocated for federal surveys to incorporate new tobacco product categories into questionnaires.⁴ We support the inclusion of e-vapor products as a new category of interest in NSDUH,⁵ and below provide further suggestions to improve the utility of tobacco use surveys.

NSDUH’s New Module Collects Useful Data on E-Vapor Use

For 2022, SAMHSA has redesigned the NSDUH tobacco module to include questions about vaping.⁶ The vaping module collects data on ever use, age of first use, past 30-day use, time of last use, number of days used in past 30 days. This would be an additional source to track e-vapor ever, past 30-day use prevalence, use patterns as well as e-vapor initiation. The 2020 Centers for Disease Control (“CDC”) National Health Interview Survey (“NHIS”) has an e-vapor module with two questions (ever and current use).⁷ Thus, NSDUH 2022 data would allow SAMHSA to track additional information on last use, number of days used, and initiations.

SAMHSA Should More Quickly Incorporate Emerging Tobacco Product Categories into NSDUH Questionnaires

Timely and comprehensive government surveys are vital tobacco harm reduction tools.⁸ To enhance the survey’s utility, SAMHSA should include questions regarding new tobacco product categories. This is particularly important in the current changing tobacco landscape. For instance, although oral-tobacco-derived-nicotine (“OTDN”) products have been available in the U.S. since 2016 and currently represent the most rapidly growing tobacco product category using traditional market measurement tools, NSDUH does not collect data on use of these

³ Request at 34,773.

⁴ See e.g. ALCS Comments to Docket No. CDC-2019-0117 (85 Fed. Reg. 3,916 January 23, 2020) – Comments on Proposed Data Collections Submitted for Public Comment and Recommendations, National Youth Tobacco Surveys 2021-2023; ALCS Comments to Docket No. CDC-2020-0037 (85 Fed. Reg. 21,234 April 16, 2020) – Comments on Proposed Data Collections Submitted for Public Comment and Recommendations, National Health Interview Survey; ALCS Comments to Docket No. CDC-2021-0023 (86 Fed. Reg. 14,115, March 12, 2021) – Comments on Proposed Data Collection Submitted for Public Comment and Recommendations. ALCS Response to RFI No. 75N95023R00001 – Request for Information: Population Assessment of Tobacco and Health (PATH) Study for the National Institute on Drug Abuse (April 5, 2021).

⁵ See ICR - FDA Submission OMB Control Number 0930-0110. Date Submitted to OIRA: 7/2/2021. Available at <https://www.reginfo.gov/public/do/PRAMain>.

⁶ Request at 34,773.

⁷ National Health Interview Survey. Questionnaires, Datasets, and Related Documentation. Available at https://www.cdc.gov/nchs/nhis/tobacco/tobacco_questionnaires.htm

⁸ See, ALCS Comments to Docket No. CDC-2020-0018 (85 Fed. Reg. 10,694 February 25, 2020) – Proposed Data Collections Submitted for Public Comment and Recommendations, Message Testing for Tobacco Communication Activities

products.⁹ Additionally, NSDUH does not collect data on heated tobacco products although other government surveys, such as the National Youth Tobacco Survey do.¹⁰

Two new survey batteries covering OTDN and heated tobacco products, asking similar questions NSDUH proposes to do with e-vapor, would be an important addition to the survey. Doing so would provide a more accurate and complete understanding of the tobacco product landscape and better inform future tobacco harm reduction policies.

A key component of FDA's Comprehensive Plan for Tobacco and Nicotine Regulation is to "account for the role of all noncombustible products,"¹¹ facilitated by "[policy] changes that will move addicted smokers down that continuum of risk to [] less harmful products."¹²

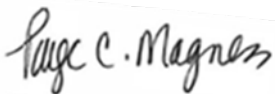
SAMHSA should incorporate emerging non-combustible product categories to help increase the survey's utility to evaluate ongoing tobacco harm reduction efforts. This is particularly important in the current changing tobacco landscape where adult tobacco consumers may shift between tobacco product categories.

Moreover, SAMHSA should accelerate availability of nationally representative data. NSDUH data collected in 2019 is not released to the public until the end of 2020. National surveys offer valuable insights into the evolving tobacco landscape and are most effective when data is timely and comprehensive.

Conclusion

We appreciate your consideration of our suggestions and we welcome the occasion to discuss this further.

Sincerely,



⁹ OTDN represents one of the fastest growing tobacco product segments in the U.S. market. *See*, Tob. Control 2019 November 21 Tobacco Companies Introduce 'Tobacco-Free' Nicotine Pouches Meagan O Robichaud, Andrew B Seidenberg, M Justin Byron.

¹⁰ CDC. National Youth Tobacco Survey. Available at https://www.cdc.gov/tobacco/data_statistics/surveys/nyts/index.htm

¹¹ Remarks by Scott Gottlieb, M.D., *Protecting American Families: Comprehensive Approach to Nicotine and Tobacco* (July 28, 2017), available at <https://www.fda.gov/news-events/speeches-fda-officials/protecting-american-families-comprehensive-approach-nicotine-and-tobacco-06282017>.

¹² *Id.*